



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/656,855 | 09/04/2003 | Nicolas C. Rivron | 1023-271US02 | 8584 |

28863 7590 03/16/2006
SHUMAKER & SIEFFERT, P. A.
8425 SEASONS PARKWAY
SUITE 105
ST. PAUL, MN 55125

| |
|----------|
| EXAMINER |
|----------|

PELLEGRINO, BRIAN E

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3738

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/656,855

Applicant(s)

RIVRON ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 12 and 14-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11,17,19,23,24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruchman et al. (5879383). Bruchman et al. disclose rubbing a vascular prosthesis (arterial graft) with a tool (swab), col. 18, lines 60-62. The examiner is interpreting the claimed elements "nodes" in this way: a node is a knob or protrusion. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Thus it can be construed that as a result of the rubbing, knobs or protrusions are formed on the luminal surface that is rubbed and would have recesses between the "node areas". Bruchman also discloses mounting the prosthesis on a mandrel, col. 18, lines 56,57. Regarding claims 19,23,24, Bruchman additionally discloses an ePTFE device has a force applied to its surface by passing pressurized water through it, col. 12, lines 23-26. It can also be construed that since ePTFE inherently possesses a microstructure of nodes and fibrils, it inherently has recesses between the nodes. Bruchman also discloses the device is porous, col. 12, lines 52-57.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Martakos et al. (5433909). Martakos et al. disclose using PTFE to form a medical device, col. 6, lines 30,31. Martakos also disclose a method of applying a force to a medical device to

form the prosthesis, col. 7, lines 9-13,43,44. Matakos discloses the PTFE having a network of nodes and fibrils that provide pores, which the Examiner is interpreting as "recesses", col. 8, lines 20-30,49,51.

Claims 11,12,19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Okuda et al. (EP 790042). Okuda et al. disclose a method of applying a force to an ePTFE medical device by rubbing a tool or rod on the luminal surface as it is inserted in the tube, page 7, line 24. It is inherent that the rubbing takes place in the transverse direction. The examiner asserts that the claimed physical properties (lifted nodes formed from the luminal surface to define a plurality of recesses) are present in the prior art material to some extent even though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art.

Claims 25-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Dzau et al. (6352555). Fig. 1 shows a vascular prosthesis (2) with a surface (6) including recesses (4) and it can be construed that the material between the recesses are nodes. The examiner is interpreting the claimed elements "nodes" in this way: a node is a point of juncture between parts. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Dzau et al. disclose the device is made of PTFE, col. 5, lines 11-13. Fig. 2 shows the device has been seeded with cells (14). Dzau et al. also disclose methods of harvesting cells for the prosthesis, col. 5, lines 19-33. Dzau et al. additionally disclose that the cells harvested are

endothelial or precursors of endothelial cells, col. 3, lines 13-22. It is inherent that the cells would be seeded less than 15 minutes after harvesting or they would not be viable much longer.

Claims 11,12,14-24,31,32 are rejected under 35 U.S.C. 102(b) as being anticipated by Sato (4596577). Sato discloses a vascular prosthesis that is a tube-shaped (Fig. 4) structure, col. 2, lines 65,66. Sato also describes the prosthesis is prepared using a mandrel (Gore patent), col. 3, lines 49-52. Sato discloses the luminal surface is rubbed with a brush having metal bristles (col. 3, lines 66,67) to lift nodes (see Fig. 3) to define a plurality of recesses. Sato additionally discloses the material for the vascular prosthesis is expanded polytetrafluoroethylene, col. 3, lines 34-36. Sato discloses the luminal surface has been rubbed, col. 4, lines 29-32. The use of "substantially perpendicular to the nodes" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited in how it can be interpreted, such that the prior can be construed to accomplish the limitation of rubbing this way. It can be construed that a pressurized fluid is applied to the surface and can be water, col. 3, lines 55-61.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14-16, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruchman et al. '383. Bruchman et al. is explained supra. Bruchman additionally

Art Unit: 3738

discloses the vascular prosthesis is everted, col. 18, line 57. However, Bruchman et al. fail to disclose an alternative tool to rub the prosthesis or that the prosthesis is everted after rubbing. It would have been an obvious matter of design choice to modify the type of tool used to rub the vessel, since applicant has not disclosed that using the particular brush or brush material provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the "brush" taught by Bruchman or the claimed wheel brush and nylon material in claim(s) 14,15 because both procedures perform the same function of applying a force across the luminal surface of a vascular prosthesis. Regarding claim 16, it is inherent that the rubbing is moving the "brush" across in a luminal direction. It would have been an obvious matter of design choice to modify the sequence of steps, since applicant has not disclosed that using the particular order of everting after rubbing provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the procedure taught by Bruchman or the claimed process of everting the prosthesis after rubbing in claim(s) 18 because both procedures perform the same function of rubbing a luminal surface of a vascular prosthesis.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okuda et al. (EP 790042). Okuda is explained supra. However, Okuda fails to disclose using a wheel brush with bristles to insert in the ePTFE tube. It is well known in the art that roughened surfaces improve cell adhesion, see WO 96/29030. It would have been an

obvious matter of design choice to modify the rod inserted in the ePTFE tube, since applicant has not disclosed that using a wheel brush to modify the surface by rubbing provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the procedure taught by Okuda et al. or the claimed wheel brush with bristles in claim(s) 22 because both devices have improved cell adhesion to the vascular prosthesis.

Response to Arguments

Applicant's arguments filed 12/27/05 have been fully considered but they are not persuasive. Applicant argues that the Okuda reference fails to disclose the method resulting in lifted nodes defining recesses. Even though Okuda is silent about the luminal surface of the tube, it is inherent that the tube already has recesses since it is porous ePTFE. The claims do not structurally define the tool or recesses and thus cannot serve to distinguish any difference between Applicant's claimed method of rubbing an inner surface of a tube or Okuda's method of rubbing an inner surface of a tube. Because the Patent & Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed invention or subject matter is unobvious, the examiner properly shifts the burden to Applicants to show that unobvious differences exist between the luminal surface, *Ex parte Phillips*, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93). In response to applicant's argument that the Dzau reference fails to show certain features of applicant's invention, it should be noted that

claims are given their broadest reasonable interpretation. The Examiner is interpreting the material between the recesses in Dzau's device to be "nodes". Clearly the material between the recesses connects the recesses. In response to applicant's argument that the Martakos reference fails to show certain features of applicant's invention, the Examiner has indicated that Martakos describes the microstructure of the device as having nodes and pores, see above. Clearly pores could be defined as recesses. Regarding Applicants' comments about the Bruchman reference, it appears the Examiner needed to clarify the interpretation of the art in view of the claims. First the disclosure in Bruchman where rubbing is done to a natural vessel can obviously be interpreted to be prepared on a vascular prosthesis, as it is well known to use grafts of vessels as replacements. Secondly, the argument to claim 19 rejected to Bruchman is not persuasive either since the claims define a pressurized force of fluid applied to the ePTFE, which as mentioned above Bruchman discloses. It is known that ePTFE has a porous structure and the pores can be construed as recesses within the nodes that Bruchman describes also mentioned above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (7am-4:30pm) and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone

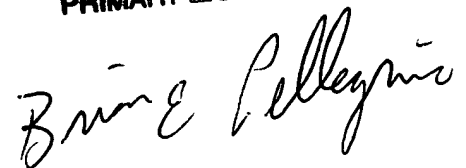
Art Unit: 3738

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

A handwritten signature in cursive script that reads "Brian E. Pellegrino".